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PROCOPIO, CORY, HARGREAVES & SAVITCH LLP
530 B STREET
SUITE 2100
SAN DIEGO, CA 92101

EXAMINER	
SKIBINSKY, ANNA	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,144	V. MARKOWITZ ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 1006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reply to Applicants

Amendments to claims 1, 8, and 15 are acknowledged. Claims currently under examination are 1-21.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 35 and 45 of copending Application No. 10/096,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1, 8, and 15 recite a method do managing and retrieving biological data by acquiring gene expression data for storage where the a quality control process is applied to mask defective data points, the data is staged and linked and then stored in a data warehouse. A user interface is provided for user query and access of data. Claims 25, 35, and 45 teach a data input file for entry of sample data, a sample and experiment data staging database, a data checking module to determine if the data meets a completeness and consistence criteria (i.e. a quality control) and data migration tool. The limitations of the recited claims in application 10/096,645 can be fully achieved with the claimed invention recited by claims 1, 8, and 15 of the instant application. Thus, though the claims of the two applications are not identical, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112-1st paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

The rejection of claim(s) 1, 8, and 15 for New Matter under 35 USC § 112-1st paragraph in the Office Action filed December 2, 2005 is withdrawn in view of Applicant's Remarks/Amendments filed April 7, 2006, 2006. Examiner acknowledges the table (Remarks, pages 11-12) specifically pointing to support for claim amendments.

2. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

3. Independent claims 1, 8, 15, recite a quality control process or module to mask defective data points within the gene expression data and to enforce a sample completion constraint. This is new matter because support for the masking of defective data points within the gene expression data and to enforcing a sample completion constraint is found during the integration step (specification, paragraph 0158). The integration step is not part of the quality control step but part of the staging and takes place after the quality validation (specification, paragraph 0064, "staging area where the data is integrated after passing data consistency and quality validation"). Thus, applying

quality control process or quality control module for masking gene expression data is new matter since this is not supported in the specification.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicants' arguments, filed April 7, 2006, have been fully considered but they are not deemed persuasive.

Claims 1, 4, 5, 8, 11, 12, 15, 18, and 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bassett et al. for reasons of record.

Bassett et al. reviews the technical and intellectual issues involved in the data processing, storing and retrieving, and analysis of gene expression information (page 51, left column, lines 37-41). An overview of the information system for large-scale genome expression experiments is depicted (Figure 1), such that physical array devices are connected/networked with data management warehouses (i.e. relational database) and interfaced with the web to provide image analysis, results & summaries, links to other databases, and accessibility to other applications (page 51, right column, lines 3-5; and page 52). Bassett et al. proposes for the construction of the data warehouse that essential information in the data warehouse can be represented into categories (i.e. separate databases within the data warehouse), wherein examples of the categories

are listed: 1) hybridization targets/DNA (fragments) sequence and identifiers (claim 1 "fragment index"); 2) details of the cell types and/or tissue origin (claim 1 "clinical database"); 3) mRNA transcript quantitation/gene expression levels (claim 1 "gene expression database"); etc. (pages 53-54, beginning on the right column, line 10). The authors indicate integration of experimental data with external information resources (i.e. Entrez) thereby allowing a user to explore (claims 1, 8, & 15 step of "querying...") the different resource nodes and to select the 'most important records' by user-defined or default criteria and then to summarize these results (claims 1, 8, 15 step of "correlating") in a condensed overview of the findings relevant to genes that are up-regulated (present/present), down-regulated (absent/absent) or both (present/absent or absent present) (claims 4, 5, 11, 12, 18, & 19; page 54, beginning on the left column, line 56). Finally, Bassett et al. describe critical aspects of the visualization/display of the genome wide expression data and state current examples of graphical displays to provide snapshots or overviews said expression data (claims 1, 8, & 15 step of "displaying..."). Thus, Bassett et al. anticipates the instantly claimed invention.

Claims recite acquiring and staging gene expression data for storage, storing the gene expression data in a data warehouse comprising three distinct databases, a clinical database for storing sample data, and a fragment index database for storing biological information and gene sequences for DNA. The staging comprises linking gene expression measurements with sample data in the gene expression and clinical databases, respectively.

Bassett et al. teach a database as well as a Data warehousing (pg. 53, col. 1, line 15). Two structures are equated (i.e. "database or 'data warehouse'") because a combination of databases remains a database. It is well known in the art that a database is a collection of files. Examiner acknowledges that a data warehouse is the combination different databases (Remarks of 2/17/05, pg. 12, lines 8-9).

As pertaining to data warehouses, Bassett et al. write that "Data from multiple sources have been integrated" to form a single data model (page 53, col. 1, lines 17-19), which fulfills the underlying concept and definition of a data warehouse. In the section "Data integration", (page 51, col 2, last paragraph) Bassett et al. specifically recited that databases such as GenBank, Entrez, and Blast, and that a "GenBank-like public database ... integrated with MEDLINE, Entrez, and other data tools ..." Entrez is recited because it can be linked with experimental information about genes on arrays and MEDLINE, a database of review articles (page 54, last paragraph of col. 1 to col. 2, line 7). Thus, this is a clear illustration of the integration of several databases to form one type of data warehouse. Additionally, in Figure 2 (pg. 53, caption lines 7-8) it is taught that micoarray experiments can be "clustered" along with gene expression data. This is another example of information from different databases being combined into one database. Furthermore, visualization techniques linked to sequence databases (pg 54, col. 2, last paragraph) are recited, which illustrates the linking of databases.

The rational database is described in the specification (pg. 30 line 20 to pg. 32 line 5) and meets the limitations of databases such as GenBank as taught in Bassett et al. Additionally, the specification does not limit data warehouses (recited in the claims)

to only those consisting of rational databases. Thus, the data warehouse, as described by Bassett et al. meets the limitations of data warehouse in the instant claims.

Claim1 recites gene expression data comprising hybridization experiment data. Bassett et al. teaches a data warehouse containing hybridization data (pg 6, line 10 of Action and page 53, col. 2, line 14 of Bassett et al.).

Claims 1, 8, and 15 have been newly amended to recite a quality control process to mask defective data points within the gene expression data and to enforce a sample completion constraint. Bassett et al. teach the refinement or "masking" of data by flagging artifacts and excluded for subsequent analysis (page 51, col. 2, lines 24-27). This is part of the quality assurance process taught, after which the refined sampled data is submitted to a database (page 51, col. 2, lines 30-35), signaling a "sample completion constraint" as recited in claim 1, line 7.

Applicants have further amended claims 1, lines 8-9, to recite staging gene expression data wherein staging comprises linking the gene expression data with sample data and a fragment index. Bassett et al. teach tools such as public databases, GenBank, and others that provided biologists with integrated and linked information (page 51, col. 2, lines 36-39). This reads of the limitations of staging gene expression data are recited by claim 1, wherein the staging of data as described in the instant specification takes place in a data warehouse "where the data is integrated after passing data consistency and quality validation. The staging area may also have a transient database ..." (paragraph 0064).

Applicants have amended claim 8, line 3 to recite a quality control module for detecting and masking defective gene expression data. However, "module" is not defined with a limiting definition or limited in the claims to being a specific type of module. As recited above, Bassett et al. teach the exclusion of artifacts during the image processing step and further teach carrying this out with software that identifies the artifacts (page 51, col. 1, lines 24-30). Fruthermore, Bassett teach the lack of quality in organism gene expression data or the incompleteness of genetic functional information (page 54, col. 2, lines 20-24) and the application of statistical analysis to detect and extract internal structure in the data available to determine what a gene does (page 54, col. 2, lines 29-33).

Reply to Arguments

Applicants argue (Remarks, page 12, lines 1-13) that Bassett et al. does not teach a system that performs a quality control function and provide no discussion of quality criteria. This is not persuasive as Applicant's not limited their claims to recite quality control using a specific criteria. Bassett et al. teach in a number of places where data is refined in order to achieve a higher quality of gene expression information (see above discussion of rejection using Bassett et al). Applicants further state that the claimed invention provides automated procedures for performing quality control before integrating the data into the data warehouse. As discussed above, Bassett et al. teach improving the data quality as a step preceding "Data integration" into databases (page 51, col. 2, Data integration section).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-12, and 15-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bassett et al. as applied to claims 1, 4, 5, 8, 11, 12, 18, and 19 above in further view of Gopalikrishnan et al. (1999).

> Bassett et al. fails to specifically recite a data warehouse constructed in a star relational schema (claims 2, 9, and 16) or a snowflake relational schema (claims 3, 10, and 17). However, Gopalikrishnan et al. describes the construction of a data warehouse in a star relational schema (page 15, lines 1-5; and Figures 2).

It would have been obvious to someone of ordinary skill in the arty at the time of the invention to practice Bassett et al. in view of Gopalkrishnan et al. who indicate that a

star or snowflake relational schema are popular representations of relational systems (pg. 11, lines 1-4).

It would be obvious to one ordinarily skilled in the art to apply star or snowflake relational schema to type the type of data warehouse taught in Bassett et al. which is not a consolidation of data from separate data sources. Furthermore, Fig. 1 shows the integration of data sources (as described, pg. 12, lines 2-3), in other words, the joining or uniting of data sources. Such data sources can be distinct databases as in the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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AS

Anna Skibinsky, PhD

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600